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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/424,521	02/15/2000	PETER E. NIELSEN	ISIS-3070	8096
32650	7590	06/17/2004	EXAMINER	
WOODCOCK WASHBURN LLP ONE LIBERTY PLACE - 46TH FLOOR PHILADELPHIA, PA 19103			SCHULTZ, JAMES	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

894.

Office Action Summary

Application No.

09/424,521

Applicant(s)

NIELSEN, PETER E.

Examiner

J. Douglas Schultz, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Application/Amendment/Claims

1. Applicant's response filed March 31, 2004 has been considered. Rejections and/or objections not reiterated from the previous office action mailed December 24, 2003 are hereby withdrawn. The following rejections and/or objections are either newly applied or are reiterated and are the only rejections and/or objections presently applied to the instant application.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Priority

3. It is noted that the first line of the specification reads "This patent application derives from International Patent Application PCT/US98/10804, filed on May 28, 1998, which claims priority to application Serial No. 08/864,765, filed on May 28, 1997 (now abandoned), which is a continuation-in-part of application Serial No. 08/595,387, filed on February 1, 1996 (now U.S. Patent No. 5,773,571), which is a continuation-in-part of application Serial No. 08/054,363, filed on April 26, 1993 (now U.S. Patent No. 5,539,082). This patent application is also a continuation-in-part of application Serial No. 08/108,591, filed on November 22, 1993 (now U.S. Patent No. 6,395,4744, which derives from International Patent Application PCT/EP92/01219, filed on May 22, 1992, published as W092/20702."

This paragraph does not constitute a proper for claiming benefit under 35 U.S.C. § 120. A proper priority claim includes a reference to the prior application as the first sentence of the specification of this application, or in an application data sheet (37 CFR 1.76), if applicant

Art Unit: 1635

intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. For example, the first page of the specification recites "This patent application derives from International Patent Application..." The last sentence of this paragraph also uses "derives from" terminology. Additionally, the above-referenced international application is said to "claim priority" to an earlier application. However, the terms "derives from" and "claims priority to" are not considered proper. Correction is required. A statement reading, for example, "This is a 371 [or national stage application] of International Application No. PCT/US98/10204, filed May 28, 1998, or "This is a continuation-in-part of application Serial No. 08/864,765, filed on May 28, 1997" or otherwise appropriate and accurate statements should be provided.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any

Art Unit: 1635

benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Claim Rejections - 35 USC § 112

4. Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The claims as amended are drawn to a peptide nucleic acid (PNA) as generically depicted in claim 23, comprising nucleobases attached to a peptide-type backbone, wherein the structure of the PNA is defined by variables comprised of numerous substitutable moieties, wherein the moieties comprising the specific variables R_i and R_j may be taken separately or together, and are selected separately or together from the group consisting of alkyl, steroid, or lipid.

Art Unit: 1635

In the claims as originally filed, “each of R_i and R_j is, independently, a lipophilic group or an amino acid labeled with a fluorescent group; or R_i and R_j , together, are a lipophilic group”. The generic recitation of a “lipophilic group” in the original claims does not provide sufficient support for the species alkyl, steroid, or lipid, as presented later in the amended claims. Furthermore, the specification as filed contains no reference to steroid or alkyl groups. Thus, the specification as originally filed is not considered to teach or fairly suggest that said lipophilic group may be composed of steroid or alkyl moieties, or any lipid.

While a rejection to this effect had been made previously and later withdrawn when applicants amended the specification to add the essential subject matter (i.e. alkyl, lipid and steroid) from a reference that had been incorporated into the specification, a further review of the incorporation by reference statement in view of M.P.E.P. § 608.01(p) and 201.06(c) makes it evident that the amendment improperly added new matter to the specification for the reasons provided below.

The instant application as filed contained a sentence incorporating by reference U.S. Patent No. 5,539,082. At the time of filing, applicants had not relied upon this patent for benefit under 35 U.S.C. § 120. Thus, this incorporation by reference statement is considered to fall under the provisions of M.P.E.P. § 608.01(p),

“Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In re de Seversky, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). In addition to other requirements for an application, the referencing application should include an identification of the referenced patent, application, or publication. **Particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found.** Guidelines for situations where applicant is permitted to fill in a number for Application No. _____ left blank in the application as filed can be found in In re Fouché, 439 F.2d 1237, 169 USPQ 429 (CCPA 1971) (Abandoned applications less than 20 years old can be incorporated by reference to the same extent as copending

Art Unit: 1635

applications; both types are open to the public upon the referencing application issuing as a patent. See MPEP § 103). (Emphasis added)

Although the specification indicates that "More recent advances in the structure and synthesis of PNAS are illustrated in WO 93/12129 and U.S. Patent 5,539,082, issued July 23, 1996, the contents of both being herein incorporated by reference", this is not considered to direct particular attention to specific portions of the referenced document where the subject matter being incorporated may be found, as required in the above citation, because such a reference is generic and *would not direct one of skill to the specific portion of the referenced document* teaching the instantly added alkyl, lipid or steroid moieties. Thus, under the guidelines of M.P.E.P. § 608.01(p), the addition to the specification of alkyl, lipid and steroid from the application corresponding to U.S. Patent No. 5,539,082 is considered to constitute new matter.

Applicant, subsequent to filing, has made a benefit claim under 35 U.S.C. § 120 claiming CIP priority to the '082 patent. Per M.P.E.P. § 201.06(c):

INCORPORATION BY REFERENCE

In a continuation or divisional application, the safeguard (petition and fee under former 37 CFR 1.60(b)) concerning the filing of an application lacking all of the pages of the specification or sheets of drawings of the prior application has not been retained in 37 CFR 1.53(b) since the specification and drawings of a continuation or divisional application are not limited to a reproduction or a "true copy" of the prior application. As a safeguard, however, an applicant may incorporate by reference the prior application by including, in the continuation or divisional application-as-filed, a statement that such specifically enumerated prior application or applications are "hereby incorporated herein by reference." The statement may appear in the specification or in the application transmittal letter. The incorporation by reference statement can only be relied upon to permit the entering of a portion of the prior application into the continuation or divisional application when the portion of the prior application has been inadvertently omitted from the submitted application papers in the continuation or divisional application. The inclusion of this incorporation by reference of the prior application(s) will permit an applicant to amend the continuation or divisional application to include any subject matter in such prior application(s), without the need for a petition provided the continuation or divisional application is entitled to a filing date notwithstanding the incorporation by reference. A priority claim under 35 U.S.C. 120 in a continuation or divisional application does not amount to an incorporation by reference of the application(s) to which priority is claimed. For the incorporation by reference to be

Art Unit: 1635

effective as a proper safeguard against the omission of a portion of a prior application, the incorporation by reference statement must be included in the specification-as-filed, or transmittal letter-as-filed, or in an amendment specifically referred to in an oath or declaration executing the application. An incorporation by reference statement added after an application's filing date is not effective because no new matter can be added to an application after its filing date (see 35 U.S.C. 132(a)). If an incorporation by reference statement is included in an amendment to the specification to add a benefit claim under 35 U.S.C. 120 after the filing date of the application, the amendment would not be proper. **When a benefit claim under 35 U.S.C. 120 is submitted after the filing of an application, the reference to the prior application cannot include an incorporation by reference statement of the prior application.** See *Dart Indus. v. Banner*, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980). Mere reference to another application, patent, or publication is not an incorporation of anything therein into the application containing such reference for the purpose of the disclosure required by 35 U.S.C. 112, first paragraph. In *re de Seversky*, 474 F.2d 671, 177 USPQ 144 (CCPA 1973). See MPEP § 608.01(p). (Emphasis added)

As is evident from the above passage, the incorporation by reference rules stated above under this section of the M.P.E.P. apply to continuations or divisionals, not to CIP's, as the instant parent is.

Assuming it is applicants' intent to find support for the entry of the new matter based upon the incorporation by reference statement to the '082 patent for benefit under 35 U.S.C. § 120, such a reliance is considered to be improper, since a benefit claim made under 35 U.S.C. § 120 after the filing date cannot include an incorporation by reference (See bold above). And since a mere reference to another patent is not an incorporation of anything into the application, it does not appear that claiming benefit under 35 U.S.C. § 120 to the '082 filing provides any support for the amendment at issue, and thus is new matter.

Specification

The amendment filed January 10, 2002 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not

Art Unit: 1635

supported by the original disclosure is as follows: the reference that variables R_i and R_j may be taken separately or together, and are selected separately or together from the group consisting of alkyl, steroid, or lipid.

Applicant is required to cancel the new matter in the reply to this Office Action.

Double Patenting

Claims 23 and 24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,773,571, and is maintained for the same reasons of record as set forth in the Office action mailed December 4, 2003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the structure of instant claims 23 and 24 is embraced by the structure of claim 1 of U.S. Patent No. 5,773,571, because the generic structure of claim 1 of U.S. Patent No. 5,773,571 teaches all the elements at all the same positions of the molecule of claims 23 and 24 of the instant application.

Applicants traverse the instant rejection by asserting that the compound of claims 23 and 24 differ from that of claim 1 of the 571 patent in at least the linking moiety "A" that connects "L" to "J". Applicants point out that in instant claims 23 and 24, the linking moiety "A" is - C(O)CH₂-. Applicants argue that only formula IIb of the patented claim could arguably provide such a linking moiety. This is agreed with.

Applicants then argue that the 571 patent further requires that compositions having formula IIb linkers have either "at least one A group of formula (IIc)" or that "at least one of y or z is not 1 or 2", which applicants argue places the claims in the 571 patent outside the instant

Art Unit: 1635

claims. However, there apparently is no (lower case) "z" in the claim. While an upper case "Y" and "Z", and a lower case "y" all appear in the claim, there does not appear to be a lower case "z" anywhere, either in the generic structure or that defined at IIb . Thus arguments that depend on the existence of a moiety which isn't evident in the claim are not considered convincing. Should this be disputed, applicants are invited to point out with particularity by page and line number where in the specification such support exists. Furthermore, even if "z" were to be located in the claim, applicants have not indicated why this alleged feature would exclude the instantly claimed structure from that of the prior art, other than by merely asserting this to be so. In the absence of such evidence the rejection is maintained.

Further, while applicants point out that instant claim 24 is directed to a peptide nucleic acid incorporated into a liposome and that claim 1 of the 571 application does not disclose a compound incorporated in a liposome, this is not considered convincing because patented claim 2 recites the structure of patented claim 1 in a liposome, much like the instant claims where claim 24 recites the structure of claim 23 in a liposome. As such, patented claim 1 is still considered to encompass the instant claims, and the rejection is maintained.

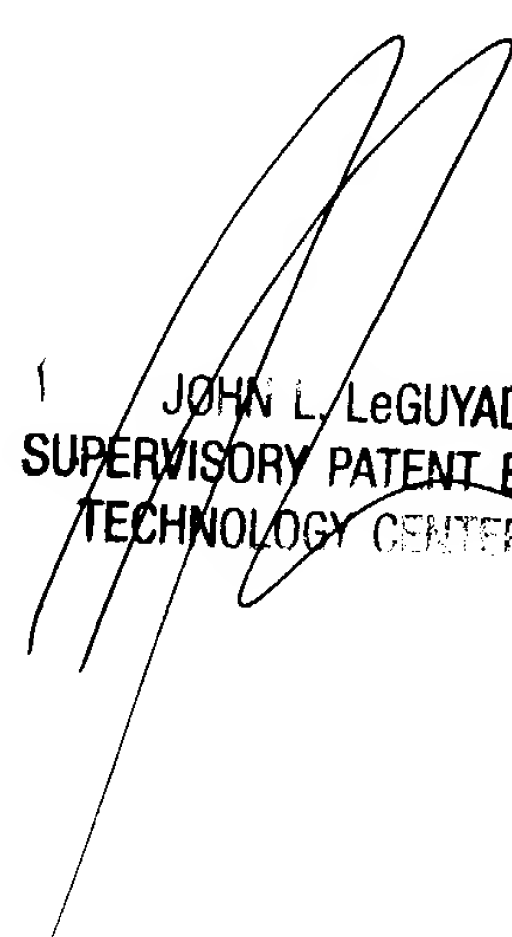
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz, Ph.D. whose telephone number is 571-272-0763. The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JD Schultz, PhD



JOHN L. LeGUYADER
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